ASSOCIATION FOR MOLECULAR PATHOLOGY
Providing global expertise in molecular testing that drives patient care
6120 Executive Boulevard, Suite 700, Rockville, Maryland, 20852
Tel: 301-634-7987 | Fax: 301-634-7995 | amp@amp.org | www.amp.org

June 12, 2023

The Honorable Cathy McMorris Rodgers
Chair
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member
House Energy and Commerce Committee
2322 Rayburn House Office Building
Washington, DC 20515

The Honorable Brett Guthrie
Chair
House Energy and Commerce Subcommittee on Health
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Anna Eshoo
Ranking Member
House Energy and Commerce Subcommittee on Health
272 Cannon House Office Building
Washington, DC 20515

Re: Pandemic Preparedness

Dear Chair McMorris Rodgers, Ranking Member Pallone, Chair Guthrie, and Ranking Member Eshoo:

On behalf of the Association for Molecular Pathology (AMP), we would like to thank you for your work to reauthorize the Pandemic and All-Hazards Preparedness Act (PAHPA). AMP is an international medical and professional association representing approximately 2,900 physicians, doctoral scientists, and medical technologists who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. Membership includes professionals from the government, academic medicine, private and hospital-based clinical laboratories, and the in vitro diagnostics industry. Our members were at the front lines of the response to the COVID-19 pandemic, providing clinical testing throughout the United States at hospitals, public health and reference laboratories, academic medical centers, and diagnostic companies.

We want to reiterate our initial comments, which advocated for codifying the laboratory response network and the inclusion of clinical laboratories, providing hazard pay for clinical laboratory professionals, and ensuring that regulatory requirements for clinical laboratories are not duplicative or burdensome, especially during a pandemic. Additionally, we offer the following comments on legislation that is being considered during the Committee's legislative hearing titled "Legislative Solutions to Bolster Preparedness and Response for All Hazards and Public Health Security Threats" for your consideration, informed by the considerable expertise of our members in the role of laboratory testing in responding to public health threats.

H.R. 3795, the Diagnostic Testing Preparedness Plan Act

We appreciate that the Committee is considering legislation that would ensure that strategies are in place "for rapid development, authorization, scaling, procurement, and distribution of diagnostics to address laboratory testing capacity during a public health emergency." Three issues that AMP believes a

testing strategy should address are 1) reprioritization of supply allocations based on clinical testing needs 2) real-time coordination amongst laboratories to leverage moments of excess capacity, and 3) removal of Institutional Review Board (IRB) barriers to accessing control samples during an emergency.

In two surveys conducted in 2020[1], AMP found that testing supply distribution was a significant limiting factor for providing diagnostic testing to the public, with over 80% of laboratories reporting that supply chain interruptions significantly delayed or decreased their testing capacity. The types of supply chain interruptions that laboratories experienced were vast and included shortages of testing platforms, testing kits, reagents, swabs, viral transport medium, laboratory consumables, and personal protective equipment. Moreover, we found that not all categories of laboratories were supported to the same degree with access to supplies, regardless of their ability to contribute significantly to testing demands. AMP was alarmed by the lack of a coordinated approach to distributing testing supplies, as this hampered the ability to meet the testing capacity needs in the United States. Furthermore, de-prioritization of hospital-based laboratories delayed testing and treatment to those patients most vulnerable to disability or death, since new treatments were often restricted to those with definitively diagnosed COVID-19 infections. When laboratories made efforts to address shortages, approximately half of the laboratory professionals that participated in our COVID-19 survey reported that the federal government was a barrier.

In particular, we urge that a strategy be flexible enough to reprioritize supply allocations based on clinical testing needs, which could change over time. Depending on the rapidly shifting needs during a public health emergency, there may be a corresponding shift in testing methodology and related supply needs. The need for testing supplies designed for acute care, surveillance, high-throughput, and other clinical needs should be monitored widely to provide real-time feedback to agencies to support data-driven supply allocations. Ideally, these monitoring systems would be proactively established, rapidly activated following novel pathogen identification, and maintained throughout the course of response.

Secondly, a national testing strategy should include real-time coordination amongst laboratories to leverage moments of excess capacity. Based on data regarding testing capacity and demand, there may be an opportunity to coordinate regionally to ensure that any excess test capacity is leveraged to ensure samples get processed as quickly as possible (e.g., a dashboard consisting of laboratories, manufacturers, and government representatives would allow real-time supply chain understanding and help to prevent communication and resource bottlenecks).

Lastly, early in the pandemic, AMP members encountered barriers to accessing samples from confirmed COVID-19 cases needed to validate their tests, which hampered the ability to meet testing capacity needs in the US. One barrier encountered was that many local institutions, e.g., hospitals, had requirements in place mandating that an IRB be convened to consider consent requirements and other ethical considerations before clinical samples from patients could be used for this purpose. This dramatically slowed institutions' and industry's ability to respond to local outbreaks, and this barrier needs to be addressed to prevent the same obstacles in future public health emergencies.

During the pandemic, the HHS Office of Human Research Protections issued guidance regarding requirements in 45 CFR part 46 that created numerous flexibilities in regard to IRB requirements.[2] While it did not specifically address the sharing of samples to serve as positive controls, it does state that

[1] https://www.amp.org/advocacy/sars-cov-2-survey/

[2] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/ohrp-guidance-on-covid-19/index.html

"Actions taken for public health or clinical purposes, and not for research purposes, are not research procedures and therefore do not require institutional review board (IRB) approval before being implemented."

AMP believes one solution would be for Congress to Direct the Office of Human Protections to issue guidance that clarifies that during future public health emergencies, the use of HIPAA de-identified samples from a hospital's clinical population for the purpose of developing and validating a diagnostic test for the pathogen for which the public health emergency has been declared is considered to be an action taken for public health under 45 CFR part 46 and thus, does not necessitate IRB review.

AMP looks forward to working with the Department of Health and Human Services (HHS) and other appropriate agencies to develop a diagnostic testing preparedness plan. However, we believe that a number of the problems that arose with testing during the COVID public health emergency were because the laboratory testing system was not fully utilized. We find that the diversity of laboratories in the United States is an enormous strength. Certified public health laboratories are essential to begin testing during an outbreak and conduct surveillance in non-emergency times. However, their limited testing capacity and lack of integration with the medical system makes it difficult for those laboratories to have a significant clinical diagnostic role. Due to their direct physical proximity to patients, hospital laboratories and other local community clinical testing laboratories are optimally positioned on the frontlines during pandemics to meet testing capacity needs, and to provide appropriate turnaround times necessary to manage patients that need immediate care. Unfortunately, our 2020 surveys found that academic medical centers and community health laboratories were underutilized and deprioritized. This is not to discredit the advantages provided by commercial reference laboratories, which often are able to perform a great number of tests. All of the sectors of the clinical testing landscape need to be supported to ensure a complete laboratory response effort during a pandemic.

To ensure that the full breadth of the laboratory testing system within the United States is factored into a diagnostic testing plan, we recommend the following changes (in red) to H.R. 3795:

On page 3:
''(2) CONTENTS.—The plan under paragraph (1) shall be designed to facilitate coordination and collaboration among—
''(A) government agencies; and
''(B) critical ~~private sector~~ diagnostic testing stakeholders, including ~~private sector clinical and diagnostic laboratories~~ State or local laboratories, professional scientific and medical societies, commercial laboratories, academic medical laboratories, community health laboratories, diagnostics manufacturers and other medical technology companies, health care product distributors, and research laboratories.

One page 3, insert the following new section and redesignate (d) as (e):
(d) CONSULTATION.—In developing the plan under subsection (a), the Secretary shall consult with State and local public health entities, professional scientific and medical societies, commercial laboratories, academic medical laboratories, community health laboratories, diagnostics manufacturers and other medical technology companies, health care product distributors, and research laboratories.

H.R. 3791, the Improving Data Accessibility Through Advancements (DATA) in Public Health Act

During the COVID-19 pandemic laboratories experienced a significant resource burden in efforts to comply with multiple local, state, and federal data reporting requirements. Further, outdated systems, e.g., use of fax machines, hindered real-time exchange of information that was critical to the country's response.

In order to reduce these burdens, AMP believes it is necessary for the Secretary of HHS to convene an expert panel comprised of members of the public health laboratory community, clinical laboratories, reference laboratories, electronic health record companies, medical technology companies, and other relevant stakeholders to standardize agency reporting format and processes for reportable infectious diseases during a pandemic, including but not limited to the following: 1) define minimal required data elements for supporting public health contact tracing; 2) establish a standardized reporting format that electronic health records and laboratory information systems vendors could adopt; 3) establish a standardized and centralized reporting agency or process that minimizes delays in return of results and eliminates the need for laboratories to duplicate reporting to multiple agencies; and 4) provide logistical support for laboratories to provide reportable infectious disease data electronically.

As such, we recommend the following changes to H.R. 3791 (in red):

Beginning on page 9:
''SEC. 310C. PUBLIC HEALTH INFORMATION SHARING AND AVAILABILITY ADVISORY COMMITTEE.
''(a) ESTABLISHMENT.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish an advisory committee, to be known as the Public Health Information Sharing and Availability Advisory Committee, to advise, and make recommendations to, the Director with respect to the implementation of public health and health care data and information reporting and sharing under section 310B.
''(b) MEMBERSHIP.—The membership of the advisory committee established pursuant to this section shall include—
''(1) individuals with subject matter expertise or experience in the following areas of public health and health care data and information, including—
''(A) State, territorial, local, and Tribal health department data systems or practices; ~~and~~
''(B) health care data, medical technology, and electronics health record systems; and
"(C) clinical laboratory testing in various settings (i.e., commercial reference, academic medical, and community hospital);
''(2) ex officio members, including from relevant Federal agencies such as the Office of the National Coordinator for Health Information Technology, the Centers for Medicare & Medicaid Services, the Centers for Disease Control and Prevention, and the Office of the Assistant Secretary for Health;
''(3) representatives of national organizations, including the Council of State and Territorial Epidemiologists, the Association of Public Health Laboratories, the Association of State and Territorial Health Officials, the National Association of County and City Health Officials, and the Big Cities Health Coalition; and
''(4) such additional members as the Secretary determines appropriate.

<u>The Biosecurity Infrastructure for Operational (BIO) Early Warning Act</u>

AMP endorsed the Tracking Pathogens Act enacted in December 2022. While AMP appreciates the interest in ensuring that the country continues to be prepared with the necessary resources, technology,

and programs to ensure early detection of emergency pathogens and other biological threats, AMP believes this program and its oversight should remain within the Centers for Disease Control and Prevention and opposes shifting its authorities to the Assistant Secretary for Preparedness and Response. For that reason, we cannot support the BIO Early Warning Act as currently drafted. **We strongly urge you to remove the word "oversee" from Sec. 5 on page 8, line 3 of the current draft and consider alternative strategies to support early disease detection than the approach currently proposed.**

Thank you again for the opportunity to submit these recommendations as you continue to work on the reauthorization of PAHPA. If AMP may be of further assistance, please do not hesitate to contact Anna Scrimenti, Associate Director of Public Policy and Advocacy at ascrimenti@amp.org

Sincerely,

Mary Steele Williams
Executive Director
Association for Molecular Pathology

CC: Representatives Greg Pence, Kim Schrier, Larry Bucshon, Andre Carson, Lauren Underwood, Ami Bera, Kathy Castor, Rosa DeLauro, Dan Crenshaw, and Scott Peters.